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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,704	06/01/2001	Randy L. Morningstar	687-442	2503

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EXAMINER
FERKO, KATHRYN P

ART UNIT	PAPER NUMBER
3743	

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/872,704	MORNINGSTAR, RANDY L.	
	Examiner	Art Unit	
	Kathryn Ferko	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-88* is/are pending in the application.

4a) Of the above claim(s) *20-51 and 62-88* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 52-61* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *03 October 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Claims 20-51 and 62-88 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7. In Paper No. 7, there seemed to be come confusion/contradiction as to the election. In a telephone conversation with Barbara Wrigley on November 14, 2002, affirmation was made to the election of Group 1A – claims 1-19 and 52-61, corresponding to that recited on page 2 of Paper No. 7.

Drawings

2. The drawings are objected to because the bend or curved portion, element 36, is not well depicted in the figures. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

4. The disclosure is objected to because of the following informalities: on page 4, the BRIEF DESCRIPTION OF THE DRAWINGS, references Figure 4. There does not appear to be a Figure 4, rather Figures 4A-4F, which are not listed. Additionally, page 7, section [0029] also mentions Figure 4. Also, page 6, section [0023] recites the inner chamber as element 82, in the last line of the section. It appears that the inner chamber

should be element 72. Furthermore, page 8, section [0030] references sidewall 78. There does not appear to be an element 78 depicted in the figures. Either the drawing need to be amended to correspond to an element 78 or the specification amended to refer to an existing figure number.

Appropriate correction is required for these and any other inconsistencies within the specification.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strother et al. in view of Copenhaver et al.

Strother et al. disclose an implantable balloon (11) having a valve portion (generally 14 with 18) with a valve body defining an inlet; a valve stem extending from the body opposite the inlet, as recited in column 3, lines 15-25 and seen in figures 1-5; a piercing (29) extending from the inlet through the body and stem; the valve constructed from a soft, elastomeric material having a memory thereby causing the piercing to remain *substantially* closed unless penetrated by a relatively rigid member, as recited in column 3, lines 60-67; a balloon portion (11) integral with the valve portion, constructed and arranged to receive and hold fluid

exiting the piercing opposite the inlet, as recited in column 4, lines 6-9; a valve stem having at least one side, as stated in column 5, lines 1-5 and seen in figures 1 and 2; a valve stem with a side and a valve portion with a sidewall laterally displaced from the valve stem side and integral with an inside surface of the balloon portion, as recited in column 4, lines 5-10, column 5, lines 1-5 and seen in figures 1 and 2; a valve that is substantially cylindrical, as recited in column 5, lines 1-2; a valve body, valve stem, and inlet that are substantially cylindrical and substantially concentric, as stated in column 3, lines 1-25, column 4, lines 5-10, column 5, lines 1-10 and seen in figures 1 and 2; a valve stem with at least one side and a piercing (29) that extends through the side of the of the stem, as recited in column 5, lines 4-6; a valve stem having a side and a valve portion with a sidewall extending from the valve body laterally from the valve stem side, as seen in figures 1 and 2; and a soft elastomeric material that is silicone, as recited in column 3, lines 50-67.

However Strother et al. do not explicitly recite a valve that is fluid tight or a valve stem with a rounded tip. On the other hand, Copenhaver et al. teach of a fluid tight valve with a slit, as stated in column 4, lines 60-62, column 6, lines 64-67, and seen in figure 2. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Strother et al. to provide a one-way valve with a slit, as taught by Copenhaver et al. for the purpose of preventing backflow. Further, it would be obvious to have the valve

stem have a rounded tip since it can be considered a matter of design choice to one with ordinary skill in the art.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Strother et al. as modified by Copenhaver et al. further in view of Dormandy, Jr. et al.

Strother et al. as modified by Copenhaver et al. disclose the invention as applied to claims 1 and 8. However, a valve body that forms a curved web, integrally connecting the valve portion sidewall and the valve stem side where the curved web is concave and opens toward the balloon portion is not explicitly recited. On the other hand, Dormandy, Jr. et al. teach a valve body that forms a curved web, integrally connecting the valve portion sidewall and the valve stem side where the curved web is concave and opens toward the balloon portion, as seen in figure 7. Therefore, it would be obvious to one with ordinary skill in the art to further modify the invention of Strother et al. as modified by Copenhaver et al. to have a valve body that forms a curved web, integrally connecting the valve portion sidewall and the valve stem side where the curved web is concave and opens toward the balloon portion, in order to relieve stress from the union of the balloon wall and the valve body.

8. Claims 11-19 and 52-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Strother et al. in view of Copenhaver et al. and further in view of Dormandy, Jr. et al.

Regarding claims 11-13 and 17, Strother et al. discloses a cylindrical valve body having a predetermined diameter and an upper side and a lower side, as

seen in figures 1 and 2; an inlet defined by the valve body lower side; a cylindrical valve stem extending upwardly from the valve body; a valve stem that has a diameter smaller than the valve body diameter, as seen in figure 2; a balloon wall extending upward of the valve body, as seen in figure 2; a piercing (29) extending from the inlet through a valve body and through a valve stem into an inner chamber that is constructed to remain closed unless a substantially rigid member is pushed through the piercing such as to inflate the balloon, as recited in column 3, lines 10-25, column 4, lines 35-67 and column 5, lines 1-26; an inlet, valve body, and valve stem that are substantially concentric, sharing a common longitudinal axis, as seen in figures 1 and 2; a piercing that follows the longitudinal axis, as seen in figures 2 and 3; and a balloon constructed entirely of silicone, as stated in column 3, line 66.

Regarding claims 52, 54-56 and 60-61, Strother et al. disclose a valve having a substantially cylindrical body defining an inlet concentric with the body, opening in a direction opposite a balloon, as seen in figure 1; a valve stem integral with the body having a substantially cylindrical side opposite the body and leading to the interior of the balloon, as recited in column 3, lines 15-25 and seen in figures 1 and 2; a piercing (29) defined by the valve body and valve stem, extending from the inlet toward the balloon and leading to the interior of the balloon, as stated in column 5, lines 1-11 and seen in figures 1-3; a cylindrical sidewall, integral with the body, extending in a direction toward the balloon; a sidewall having an external surface attachable to the balloon, as seen in figure 1;

an end portion, integral with and extending from the sidewall, which curves inwardly to define an opening that has an inner diameter that is smaller than an inner diameter of the cylindrical sidewall, as seen in figure 2; a cylindrical wall having a lower sidewall and an upper sidewall and a taper connecting the lower sidewall and the upper sidewall whereby the lower sidewall has a larger diameter than an outside diameter of the upper sidewall, where in the closed state the taper of Strother et al. reduces the diameter, as seen in figure 2; an upper sidewall and a lower sidewall that have substantially equal inner diameters, wherein when opened by the rigid member the inner diameters will be substantially the same; a valve that is unitarily constructed from an elastomeric material; and a valve that is unitarily constructed from elastomeric material, as stated in column 3, lines 60-67.

However, regarding claims 11-19, Strother et al. do not explicitly recite a balloon having an inner diameter, while in a deflated state, which is larger than the valve stem diameter such that an annular space exits between the balloon wall and the valve stem while the balloon is deflated; the annular space relieving stress from a union of the balloon wall and the valve body when the balloon is inflated; a piercing that prevents a fluid from escaping from the inner chamber; a piercing with a curved portion; a piercing with a straight portion and a curved portion where the straight portion extends upwardly from the inlet and substantially parallel to the axis while the curved portion extends from the straight portion to a side portion of the valve stem; an annular space that is defined on a

lower side by a curved web which is concave and opening upwardly; a removable skirt extending downwardly from the valve body providing a surface that may be handled during a balloon manufacturing operation without damaging the balloon wall or valve body; or a removable skirt with an outside diameter smaller than an outside diameter of the valve body such that a ridge is formed between the valve body and the skirt.

Regarding claims 50-61, Strother et al, do not explicitly recite, a valve stem having a rounded tip; a cylindrical sidewall radially displaced from the stem side creating an annular space between the stem and the sidewall; a valve body having a curved portion, concave so as to open toward the balloon interior, connecting the sidewall with the stem; a skirt extending from the body in a direction opposite the balloon; a skirt with an outer diameter smaller than an outer diameter of the valve body, thereby providing a visual and tactile definition of an extent of the skirt, such that the skirt may be removed with out removing material from the valve body; or a skirt that is sized to frictionally fit within an open end of a dipping tube.

On the other hand, with regard to claims 11, 16, and 52-53, Dormandy, Jr. et al. teach a balloon having an inner diameter, while in a deflated state, which is larger than the valve stem diameter such that an annular space exits between the balloon wall and the valve stem while the balloon is deflated; the annular space relieving stress from a union of the balloon wall and the valve body when the balloon is inflated, as seen in figure 7; and an annular space that is defined

on a lower side by a curved web that is concave and opening upwardly; a cylindrical sidewall, radially displaced from the stem side, thereby creating an annular space between the stem and the sidewall; an a curved portion that is concave so as to open toward the balloon interior, connecting the sidewall and with the stem, as seen in figure7. Therefore, it would be obvious to one with ordinary skill in the art at the time the invention was made to modify the invention of Strother et al. to incorporate an annular space for the purpose of relieving stress.

Additionally, regarding claims 11, 14-15, and 52, Copenhaver et al. teach a piercing preventing a fluid from escaping from the inner chamber, as recited in column 4, lines 60-65; a piercing with a curved portion, as seen in figure 2; a piercing with a straight portion and a curved portion where the straight portion extends upwardly from the inlet and substantially parallel to the axis while the curved portion extends from the straight portion to a side portion of the valve stem; and a piercing with a bend that curves toward the stem side, as seen in figure 2. Therefore, it would be obvious to further modify the invention of Strother et al. to include a curved piercing that recloses to prevent fluid backflow.

Furthermore, regarding claims 18-19, and 57-59, a removable skirt extending downwardly from the valve body providing a surface that may be handled during a balloon manufacturing operation without damaging the balloon wall or valve body; a removable skirt with an outside diameter smaller than an outside diameter of the valve body such that a ridge is formed between the valve

body and the skirt; a skirt extending from the body in a direction opposite the balloon; a skirt with an outer diameter smaller than an outer diameter of the valve body, thereby providing a visual and tactile definition of an extent of the skirt, such that the skirt may be removed with out removing material from the valve body; and a skirt that is sized to frictionally fit within an open end of a dipping tube are known manufacturing techniques that would be obvious to one with ordinary skill in the art, and thus, fall within the scope of the invention.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure are as follows: US Patent No. 4,697,584; US Patent No. 5,517,979; US Patent No. 6,379,329; US Patent No. 4,545,367; US Patent No. 5,558,829; US Patent No. 6,050,934; US Patent No. 6,293,923; US Patent No. 5,358,001; US Patent No. 6,312,405; US Patent No. 5,934,310; US Patent No. 2,731,028; and US Patent No. 5,624,395.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn Ferko whose telephone number is (703) 306-3454. The examiner can normally be reached on M-F (7:30-5:00) First Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A Bennett can be reached on (703) 308-0101. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1113.

KF
November 20, 2002

Henry Bennett
Supervisory Patent Examiner
Group 3700